Paper No. 34

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte BARRETT ROLLINS and CHARLES STILES

Appeal No. 2001-0869
Application No. 08/453,347

ORDER UNDER 37 CFR § 1.196(d)

Before STONER, Chief Administrative Patent Judge, HARKCOM, Vice Chief Administrative Patent Judge, and WILLIAM F. SMITH, Administrative Patent Judge.

WILLIAM F. SMITH, Administrative Patent Judge.

Prior to a merits panel reaching the merits of the issues raised in this appeal, appellants need to respond to respond to the following issues.

1. Interference No. 103,998.

Interference No. 103,998 ('998 Interference) involved U.S. Patent No. 5,179,078 ('078 patent) and Application 07/330,446 (Yoshimura). The '078 patent is stated to be a parent application of the present application. The sole count in the '998 Interference reads as follows:

A method of treating neoplasms or tumors in humans comprising administering an effective amount of a purified human JE-MCP-1 protein.

Claims 1, 2, 5, and 6 of the '078 patent were stated to correspond to the count. The inventors of the '078 patent conceded priority to Yoshimura. In accordance with the concession, judgment was entered against the inventors of the '078 patent, i.e., the inventors of the '078 patent were not entitled to a patent containing claims 1, 2, 5, and 6 of the '078 patent which corresponded to the count. Claims 1, 2, 5, and 6 of the '078 patent read as follows:

1. A method of suppressing tumor formation in a mammal comprising administering to said mammal a therapeutically affective [sic] amount of JE/Monocyte Chemoattractant Protein-1 (JE/MCP-1).

2. A method of increasing a monocyte mediated tumoricidal activity in a mammal comprising administering to said mammal an effective amount of JE/Monocyte Chemoattractant Protein-1.

5. A method of suppressing tumor formation in a mammal comprising administering to said mammal tumor killing cells which express JE/Monocyte Chemoattractant Protein-1.

6. A method of claim 5, wherein the tumor killing cells are tumor infiltrating lymphocytes.

Claims 1, 3, and 4 pending in this application read as follows:

1. A method of suppressing tumor formation in a mammal comprising administering to said mammal tumor killing cells which have been genetically engineered to express JE/monocyte chemoattractant protein-1 when present in the mammal.

3. A method of increasing monocyte mediated tumoricidal activity in a mammal comprising administering to said mammal a therapeutically effective amount of mammalian cells that express JE/monocyte chemoattractant protein-1 when present in the mammal.

4. A method of treating a localized side-effect of malignancy in a mammal comprising locally administering to the mammal a therapeutically effective amount

mammalian cells that have been genetically engineered to express JE/monocyte chemoattractant protein-1 when the cells are present in the mammal.

Claims 2, 5, and 7 through 13 of this application depend directly or indirectly from these claims.

Having judgment entered against them in the '998 Interference, there are two issues which appellants need to address in this application, i.e., whether an estoppel exists under 37 CFR § 1.658(c) and whether any of the claims on appeal are patentably indistinguishable from the count of the '998 Interference. See In re Deckler, 977 F.2d 1449, 24 USPQ2d 1448 (Fed. Cir. 1992). These issues must be considered given the relationship between certain of the pending claims and the claims of the '078 patent which corresponded to the count in the '998 Interference as well as the count of that Interference.

For example, claim 1 on appeal appears identical to claim 5 of the '078 Patent which corresponded to the count in the '998 Interference except that claim 1 in this appeal states that the tumor killing cells were "genetically engineered." It is unclear how claim 1 on appeal is patentably distinguishable from claim 5 of the '078 patent on that basis. Thus, an estoppel under 37 CFR § 1.658(c) appears to exist in regard to claims such as claim 1 on appeal. In other words, having lost claim 5 of the '078 patent, it is not clear on what basis appellants are entitled to claims such as claim 1 of this application.

Furthermore, in comparing claim 3 on appeal with claim 5 of the '078 patent, it may be that claim 3 is patentably indistinguishable from the count of the '998

Interference. If so, such claims would be unpatentable on the basis of the court's holding in Deckler.

Within the time period set forth below, appellants are to file a Supplemental Appeal Brief which explains with specificity for each claim pending in this application their views as to why an estoppel does not exist under 37 CFR § 1.658(c) and why the claims are not unpatentable on the basis of the principles set forth in Deckler.

2. Claim 6.

Claim 6 reads as follows:

6. A method of combatting [sic] a parasitic infection in a mammal comprising administering to the mammal a therapeutically effective amount of mammalian cells that express JE/monocyte chemoattractant protein-1 when present in the mammal.

In reviewing the specification of this application, the most relevant disclosure in regard to this particular embodiment of the present invention appears at page 3, lines 11-16 as follows:

> The presence of JE/MCP-1 in vivo is accompanied by a local increase in the presence of eosinophils. Therefore, another aspect of the subject invention comprises methods of combatting [sic] a parasitic infection in a vertebrate animal by administering to that vertebrate an effective amount of JE/MCP-1.

It is not clear on what basis one would conclude that a local increase in the presence of the eosinophils would be considered useful in combating a parasitic infection in a vertebrate animal.

The Supplemental Appeal Brief filed in response to this order is to contain a section addressing this issue. Appellants should explain why one skilled in the art would conclude that any active agent that results in a "local increase in the presence of eosinophils" necessarily is useful in combating a parasitic infection in a vertebrate

animal. Appellants' statement should be factually supported and a copy of all documents relied upon in support of the statement be supplied.

3. Appeal No. 1997-2529, Application No. 08/228,931.

Application No. 08/228,931 ('931 application) was the subject of Appeal No. 1997-2529. In an opinion entered September 28, 2001, a merits panel affirmed the examiner's rejection of the claims pending in that application under 35 U.S.C. § 112, first paragraph (enablement). Claims 1, 18, and 27 of the '931 application as edited and reproduced in the Board's opinion in the previous appeal read as follows:

1. A purified human JE factor polypeptide substantially free from co-produced polypeptides.

18. A recombinant human JE factor comprising an amino acid sequence from about amino acid #30 to amino acid #99 of Table 1 or biologically active fragment or mutation thereof.

27. A purified human JE factor comprising an amino acid sequence from about amino acid #30 to amino acid #99 of Table 1 or biologically active fragment or mutation thereof.

As seen, the claims under review in the previous appeal were directed to or required the presence of a purified human JE factor polypeptide. In the previous appeal, we noted that the USPTO had issued a related application, 08/046,243 as U.S. Patent No. 5,278,287 ('287 patent). Claim 1 of the '287 patent reads as follows:

1. A purified human JE factor polypeptide comprising an amino acid sequence from amino acid #30 to amino acid #99 of Table I.

As stated in the paragraph bridging pages 6-7 of the opinion entered in the previous appeal:

> In considering the issues raised in this appeal, we have taken into account that claim 1 of the '287 patent reflects the USPTO's determination that purified human JE factor polypeptide comprising an amino acid sequence from amino acid #30 to amino acid #99 of Table I of this application is patentable and therefore is presumable enabled. 35 U.S.C. § 282. We will not look behind that determination in this appeal proceeding. Rather, we will limit out consideration in this appeal to the issue of whether the specification of this application and relevant prior art enables one to make and use the polypeptides included within the claims on appeal beyond those having "amino acid sequence from amino acid #30 to amino acid #99 of Table I."

To be consistent, it appears the same approach needs to be taken in this appeal, i.e., the merits panel should not look behind the fact that claim 1 of the '073 patent has been determined to be enabled by the USPTO. Rather, it appears proper that the merits panel focus on those embodiments of the pending claims which extend beyond the scope of claim 1 of the '073 patent. If that approach is taken, it appears that a number of the enablement issues raised in this appeal are similar to the enablement issues raised by the examiner in the previous appeal which constituted the basis of the affirmance of the prior enablement rejection.

The claim embodiments found to be non-enabled in the previous appeal were those human JE factor polypeptides directed to allelic variations, mutations, and biologically active fragments. All of the claims pending in this application include embodiments which require the presence or use of human JE factor polypeptides which

are allelic variations, mutations and biologically active fragments of the JE protein. Thus, to the extent that those embodiments were determined to be non-enabled in the previous appeal, it appears the same enablement problems exist with the present claims.

Appellants did not request reconsideration of the decision in the previous appeal and according to current USPTO records that application is abandoned and is not subject to continuing prosecution.

The Supplemental Appeal Brief to be filed must explain why the affirmance of the enablement rejection in the previous appeal should not be considered controlling in determining whether the claims pending in this application are enabled under 35 U.S.C. § 112, first paragraph, to the extent the claims include allelic variations, mutations, or biologically actor fragments of the JE/monocyte chemoattractant protein-1.

4. Missing Exhibits

On pages 4-6 of the Appeal Brief, appellants indicate 39 exhibits were attached to the Appeal Brief. Unfortunately, the exhibits are no longer associated with the file. Appellants are asked to resubmit Exhibits 2, 4, 12, 13, 17-21, and 26-38 with the Supplemental Appeal Brief. Appellants cooperation in this matter is appreciated.

Time Period for Response

A time period of TWO MONTHS is set for appellants to file a Supplemental Appeal Brief required by this order. As set forth n 37 CFR § 1.196(d), this time period is non-extendable. If the Supplemental Appeal Brief is not filed within the time period set, the appeal will be dismissed as to all claims pending.

Bruce H. Stoner, Jr. Administrative Patent Judge	)
Gary V. Harkcom Administrative Patent Judge	) BOARD OF PATENT)) APPEALS AND)) INTERFERENCES
William F. Smith Administrative Patent Judge	)

Hamilton, Brook, Smith & Reynolds, P.C.
530 Virginia Road
P.O. Box 9133
Concord, MA 01742-9133

dem